K071187

510(K) Summary

DEVICE NAME:

MicroFuse™ Bone Void Filler

SUBMITTED BY:

DEC 2 0 2007

Globus Medical Inc.
Valley Forge Business Center
2560 General Armistead Ave.
Audubon, PA 19403
(610) 415-9000 x1670
Contact: Kelly J. Baker

CLASSIFICATION:

Per 21 CFR §888.3045: Resorbable Calcium Salt Bone Void Filler. Class II. The Product Code is MQV. The Panel Code is 87.

PREDICATE DEVICES:

Medtronic Sofamor Danek MasterGraft K012506, SE date March 7, 2002;
OsteoBiologics PolyGraft BGS K040047, SE date Dec 17, 2004; and
Kensey Nash Bone Void Filler K060917, SE date Sept 22, 2006.

DEVICE DESCRIPTION:

MicroFuse™ Bone Void Filler is a porous bone graft scaffold composed of bonded poly (lactide-co-glycolide) or poly(lactic acid) microspheres. MicroFuse™ is available with and without calcium sulfate. MicroFuse™ is provided in a variety of shapes and sizes, in the form of granules, sheets, and pre-formed blocks. MicroFuse™ granules are designed to be gently packed into contained voids or defects. MicroFuse™ sheets are designed to be used with shallow bony defects, or as a bone graft only to cover a defect. MicroFuse™ blocks are designed to fill an entire defect. MicroFuse™ implants are available in short-term (ST), mid-term (MT), or long-term (LT) compositions.

INTENDED USE:

MicroFuse™ Bone Void Filler, combined with autograft or bone marrow aspirate, is intended for use in filling bony voids or gaps of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or created from traumatic injury to the bone. MicroFuse™ provides a bone void filler that resorbs and is replaced with bone during the healing process.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The MicroFuse™ Bone Graft Substitute is similar to the predicate devices with respect to design, indications for use, principles of operation, and performance.

Attachment G: Revised Device Specific Insert

IMPORTANT INFORMATION ON MICROFUSE™ BONE VOID FILLER

GLOBUS MEDICAL **DI115A**

DESCRIPTION

MicroFuse™ Bone Void Filler is a porous bone graft scaffold composed of bonded poly (lactide-co-glycolide) or poly(lactic acid) microspheres. MicroFuse™ is available with and without calcium sulfate. MicroFuse™ is provided in a variety of shapes and sizes, in the form of granules, sheets, and pre-formed blocks. MicroFuse™ granules are designed to be gently packed into contained voids or defects. MicroFuse™ sheets are designed to be used with shallow bony defects, or as a bone graft only to cover a defect. MicroFuse™ blocks are designed to fill an entire defect. MicroFuse™ implants are available in short-term (ST), mid-term (MT), or long-term (LT) composition.

INDICATIONS

MicroFuse™ Bone Void Filler, combined with autograft or bone marrow aspirate, is intended for use in filling bony voids or gaps of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or created from traumatic injury to the bone. MicroFuse™ provides a bone void filler that resorbs and is replaced with bone during the healing process.

CONTRAINDICATIONS

This product is not intended to provide structural support during the healing process therefore MicroFuse™ is contraindicated where the device is intended as structural support in the skeletal system. Conditions representing relative contraindications include:

1. Severe neurological or vascular disease
2. Uncontrolled diabetes
3. Hypercalcemia
4. Pregnancy
5. Where fracture stabilization is not possible
6. When there are systemic and/or metabolic disorders that affect the bone or wound healing
7. Any patient unwilling to follow postoperative instructions
8. Any case not described in the indications

POTENTIAL ADVERSE EVENTS

A listing of potential adverse events includes but is not limited to:

1. Deformity of the bone at the surgical site

2. Fracture or extrusion of the MicroFuse™ implant(s), with or without generation of particulate debris
3. Wound complications including hematoma, site damage, infection, bone fracture, and other complications common to any surgical procedure
4. Incomplete, or lack of, osseous ingrowth into bone void, as possible with any bone void filler

WARNINGS AND PRECAUTIONS
A successful result is not always achieved in every surgical case.

As with any surgical procedure, care should be demonstrated in treating patients with preexisting conditions that may impact the success of the surgical procedure. This includes patients with bleeding disorders of any etiology, long-term steroid therapy, or immunosuppressive therapy, or high dose radiation therapy.

MicroFuse™ implants are not designed with sufficient mechanical strength to support reduction of a defect site prior to soft and hard tissue ingrowth. Rigid fixation methods are recommended as needed to ensure stabilization of the defect. Complete postoperative wound closure is essential.

Use this device as supplied and in accordance with the handling and use information provided below.

WARNING: Never use this device if the vial or package is cracked or broken.

HANDLING & USE
MicroFuse™ implants are provided sterile and should be considered sterile unless the inner packaging has been opened or damaged. This product is never to be resterilized. This device is for single patient use and should never be reused.

MicroFuse™ implants are intended to be combined with autogenous bone graft material or bone marrow aspirate, and may also be used with blood, or sterile fluids, such as saline. MicroFuse™ slotted blocks must be gently packed with autogenous bone graft material, and may also be packed with additional materials as described above.

MicroFuse™ sheets may be made temporarily flexible by heating the sheets to 60°C during surgery using a sterile hot water bath. Flexible sheets may then be placed at the surgical site and contoured to provide a custom fit. If re-heating is necessary, sheet may be removed from the site and heated again in the sterile hot water bath. [Note: MicroFuse™ sheets may be combined with blood, bone marrow aspirate, or other sterile fluids as described above, however these liquids should only be added to the sheet after the heating and shaping process is complete. Immersion of a blood or marrow soaked implant into a hot water bath

may rinse the blood or bone marrow aspirate out of the implant].

MicroFuse™ should be implanted into bony defects according to the following technique. Prepare the walls of the defect that will contact the MicroFuse™ product, as needed. Mix or saturate the MicroFuse™ product with autologous bone or bone marrow aspirate. Add blood or sterile fluids such as saline if desired. Gently pack the site, but avoid overfilling the bone void or compressing the treatment site. Remove excess material from the treatment site. Close the site using standard closure techniques and discard any unused MicroFuse™ product.

PACKAGING
MicroFuse™ packaging should be intact upon receipt. Damaged packages or products should not be used, and should be returned to Globus Medical.

CAUTION: Federal Law Restricts this Device to Sale by or on the order of a Physician

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Globus Medical Inc.
% Ms. Kelly J. Baker
Valley Business Center
2560 General Armistead Avenue
Audubon, PA 19403

DEC 2 0 2007

Re: K071187
Trade/Device Name: MicroFuse™ Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Names: Resorable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: September 21, 2007
Received: September 24, 2007

Dear Ms. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K071187

Device Name: MicroFuse™ Bone Void Filler

INDICATIONS:

MicroFuse™ Bone Void Filler, combined with autograft or bone marrow aspirate, is intended for use in filling bony voids or gaps of the extremities and pelvis that are not intrinsic to the stability of the bony structure. These osseous defects may be surgically created or created from traumatic injury to the bone. MicroFuse™ provides a bone void filler that resorbs and is replaced with bone during the healing process.

Prescription Use __X__ OR Over-The-Counter Use____
(Per 21 CFR §801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorati
and Neurological Devices

510(k) Number K071187